K102392

510(k) Summary: MicroFuse® Additional Implants

DEC 22 2010

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
(610) 415-9000

Contact: Kelly J. Baker, Ph.D.
Director, Clinical Affairs & Regulatory

Date Prepared: August 20, 2010

Device Name(s): MicroFuse® Putty and MicroFuse® ST MIS

Classification: Per 21 CFR as follows:
§888.3045: Resorbable Calcium Salt Bone Void Filler
Product Code is MQV
Regulatory Class II Panel Code 87.

Predicate(s): MicroFuse® Bone Void Filler (K071187, K082442 and K083232)

Purpose:
The purpose of this submission is to add MicroFuse® additional implants (Putty and ST MIS) to the MicroFuse® product line.

DEVICE DESCRIPTION:
MicroFuse® Bone Void Filler is a porous bone graft scaffold composed of bonded poly (lactide-co-glycolide) or poly(lactic acid) microspheres. MicroFuse® is available with and without a combination of barium sulfate and calcium sulfate. MicroFuse® is provided in a variety of shapes and sizes, in the form of granules, sheets, pre-formed blocks, putty and ST MIS implants. MicroFuse® ST Granules and putty are designed to be gently packed into contained voids or defects. MicroFuse® Sheets are designed to be used with shallow bony defects, or as a bone graft onlay to cover a defect. MicroFuse® Blocks and ST MIS implants are designed to fill an entire defect. MicroFuse® Putty is composed of MicroFuse® ST Granules combined with an inert biodegradable carrier. MicroFuse® implants are available in short-term (ST), mid-term (MT), or long-term (LT) composition.

Indications for Use:
MicroFuse® Bone Void Filler is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. MicroFuse® Bone Void Filler may be combined with autogenous bone marrow aspirate or autograft. MicroFuse® Putty is a bone graft extender to be used with autogenous bone marrow aspirate and autograft. MicroFuse® is intended to be gently packed into bony voids or gaps of the skeletal system (e.g. the spine, pelvis, and extremities). These osseous defects may be surgically created or created from traumatic injury to the

bone. MicroFuse® provides a bone void filler that resorbs and is replaced with bone during the healing process.

Performance Data:
MicroFuse® additional implants satisfy molecular weight testing, carrier degradation testing, biocompatibility testing, shelf life testing, pH testing, and animal testing, and special controls provided in the *Guidance for Industry and FDA, Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device, Issued June 2, 2003.*

Basis of Substantial Equivalence:
The MicroFuse® additional implants are similar to the predicate device(s) with respect to design, indications for use and principles of operation. The information provided within this premarket notification supports substantial equivalence to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

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Globus Medical Inc.
% Kelly J. Baker, Ph.D.
Director, Clinical Affairs and Regulatory
2560 General Armistead Avenue
Audubon, Pennsylvania 19403

Re: K102392
Trade/Device Name: MicroFuse® Putty and MicroFuse® ST MIS
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: November 24, 2010
Received: November 26, 2010

Dear Dr. Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K102392

Device Name: MicroFuse® Putty and MicroFuse® ST MIS

Indications:

MicroFuse® Bone Void Filler is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. MicroFuse® Bone Void Filler may be combined with autogenous bone marrow aspirate or autograft. MicroFuse® Putty is a bone graft extender to be used with autogenous bone marrow aspirate and autograft. MicroFuse® is intended to be gently packed into bony voids or gaps of the skeletal system (e.g. the spine, pelvis, and extremities). These osseous defects may be surgically created or created from traumatic injury to the bone. MicroFuse® provides a bone void filler that resorbs and is replaced with bone during the healing process.

Prescription Use __X__ OR Over-The-Counter Use____
(Per 21 CFR §801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102392